Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. As well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product.The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, which can be used repeatedly.

WARNING:

- **Discomfort or pain may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the pulse oximeter should not be used on the same finger for more than 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not look at the light source.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

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1 Safety

1.1 Instructions for safe operations

✧ Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance.It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using the device.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

✧ The oximeter cannot be used together with devices not specified in User's Manual. Only the accessory that is appointed or recommendatory by manufacture can be used with this device.

✧ This product is calibrated before leaving factory.

1.2 Warning

Explosive hazard—DO NOT use the oximeter in the environment with tinder such as anesthetic.

DO NOT use the oximeter while the patient is being scanned by MRI or CT.

The person who is allergic to rubber can not use this device.

The disposal of scrap instrument and its accessories and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

Please choose the accessories which are appointed or recommended by the manufacturer for avoiding device damage.

Please don't measure this device with functional tester for the device's related information.

Prevent children from swallowing the product or its accessories.For children users,please use the product under the condition of adult guardianship.

When installing or removing the battery,do not wear electric articles on hands to prevent from short circuit and burning the skin.

It is not recommended to use the device in high frequency environment.

In the area where the blast is easy to happen because of potential factor,don't take out,install or charge the battery in order to avoid blast or fire.

Please charge the battery in the room temperature environment.

In addition,the overall check of monitor,including the safety check such as the leakage current ,should be performed only by qualified personnel once every 12 months.

1.3 Attention

Keep the oximeter away from dust, vibration, corrosive substances, tinder, high temperature and moisture.

If the oximeter gets wet, please stop operation.

When it is carried from cold environment to warm or humid environment, please do not use it immediately.

- DO NOT operate button on front panel with sharp things.
- High temperature or high pressure steam disinfection for the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1) for cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- The fingers which are too thin or too cold may affect the measure accuracy , please clip the thicker finger such as thumb and middle finger deeply enough into the probe.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measure value when the waveform on screen is equably and steady-going. This measure value is optimal value,and the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull the finger out and reinsert to restore normal use.
- The device has normal life for three years since the first electrified use.
- The device has pulse sound indication function.Please check the chapter 6.1 as reference.
- The device has the function of beyond limit alarm.When the measure data is beyond the highest or lowest limit, the device would start alarm automatically .
- The device has the alarm function, this function can be suspended.Please check the chapter 6.1 as reference.
- The device may be not fit for all patients.If you are unable to receive approving measure, discontinue use.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration. A number of diseases relating to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life.Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

The Pulse Oximeter is small in volume,low in power consumption,convenient in operation and portable.It is only necessary for patient to put one finger into probe for diagnosis, and the display screen will directly show the SpO_2 value with the high veracity and repetition.

2.1 Features

A Novel appearance,more fit for children.

B Small in volume, light in weight and convenient in carrying.

C Low power consumption

2.2 Major applications and scope of application

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.The product is fit for family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports and it is not recommended to use the device during the process of having sport) and etc.

⚠ **The problem of overrating would emerge when the patient is suffering from toxicosis which is caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment requirements

Storage Environment

a) Temperature :-40℃～+60℃
b) Relative humidity :5%～95%
c) Atmospheric pressure :500hPa～1060hPa

Operating Environment

a) Temperature :10℃～40℃
b) Relative Humidity :30%～75%
c) Atmospheric pressure:700hPa～1060hPa

3 Principle

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor.Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

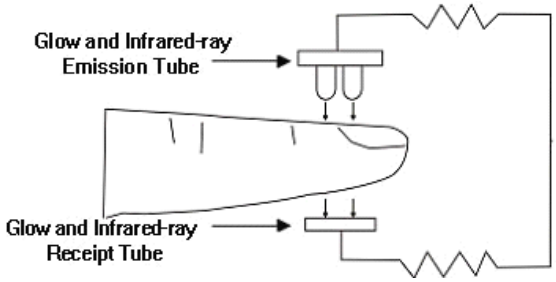

Figure 1 Work elements

4 Technical specifications

4.1 Main performance

- SpO_2 value display,Pulse rate value display
- Bar graph display
- Pulse waveform display

- Pulse sound indication
- Low-power indication: when the battery is low in power,the symbol will blink.
- With alarm function
- With screen overturn function

4.2 Main parameters

A Measurement of SpO_2

Measuring range: 0%～100％

Accuracy: 70~100%:±2%;Below 70%:unspecified.

B Measurement of pulse rate

Measuring range:30bpm～250bpm

Accuracy: ±2 bpm or ±2% (select larger)

C Resolution

SpO_2 : 1%, Pulse rate: 1bpm

D Measurement performance in weak filling condition:

SpO_2 and pulse rate can be detected correctly when pulse-filling ratio is 0.4%.SpO_2 error is ±4%; pulse rate error is ±2 bpm or ±2% (select larger).

E Resistance to surrounding light:

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F Power supply requirement: 3.6 V DC ~4.2V DC.

5 Installation

5.1 View of the front panel

Figure 2. Front View

5.2 Battery installation

Figure 3.Battery installation

A. Refer to the polarity and put the edge of the battery on the mouth of the battery box ,along the bottom of the battery box, gently push the battery into the box until the whole battery has been in-place.(Refer to Figure 3)

B. Replace the cover.

⚠ **Please take care of the polarity when you insert the battery for the improper insertion may damage the device.**

5.3 Accessories

A. One rechargeable buttony battery(Type: LiR2450)

B. Charge accessories: One power adapter（Type: CMS0105）, one charger（Type: LiCh-10）, one data line（Type: USB-AM To USB-miniBM）

C. One user manual

D. One lanyard

6 Operating Guide

6.1 Application method

6.1.1 Basic operation

a. Open the battery cover,and put the buttony battery in the battery box,then replace the cover.

b. Insert one finger into the probe of the device.

c. Long press the button to turn the device on, and the measure interface appears after the device self-test.

d. Do not shake the finger and try to keep the patient still during the process.

e. The data can be read directly from the display screen in the measuring interface.

Figure 4 Finger placement

⚠Fingernails and the luminescent tube should be in the same side.

6.1.2 Pulse sound setting

After turning the device on,the pulse sound is open.Long press the button can close the pulse sound and the pulse sound indication icon disappears.Long press button again, the pulse sound is turned on and pulse sound indication icon appears.

6.1.3 Alarm setting

a. Alarm includes the alarm of measure data's going beyond the limits (When the SpO_2 is below 90%, or the pulse rate is not between 50bpm and 120bpm,the alarm occurs), the alarm of low-power.
b. In the open state of alarm,when the measure data is beyond the the normal measure range, the device would give alarm sound and the corresponding value glitter.Alarm could be suspended by short pressing button,and the alarm icon disappears,but the value still glitter.Alarm function will be renewed in 30 seconds.

⚠ If low-power alarm occurs,please charge the battery;and if the battery has been out of normal life ,please replace it by a new one.

6.1.4 Display mode switch

In the normal measure or alarm pause state,short press the button can switch the display mode of the screen.

6.1.5 Charge

Put the rechargeable buttony battery properly according to the polarity direction in the charger.
Connect one end of the adapter to the power supply socket,and connect another end of the adapter to charger by data line.

⚠ The power adapter of the device accords with the requirements of IEC 60601-1.

⚠ The charger accords with the requirements of IEC 60601-1.

⚠ In charging state, the red indication light of the charger will shine,the green indication light of the charger shining means the charge has been accomplished.

6.2 Attention for operation

A. Please check the device before using, and confirm that it can work normally.

B.The finger should be in a proper position (see the attached illustration of figure 4 for reference), or else it may result in inaccurate measure.

C.The ray between luminescent tube and photoelectric receiving tube must get across subject's arteriole.

D. The oximeter should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.

E. Ensure nothing, such as a plaster, can impede the light passage., or else it may result in inaccurate

measure of SpO_2 and pulse rate.

F. Excessive ambient light may affect measurement accuracy. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.

G.Intense activity of the subject or extreme electrosurgical interference may also affect the accuracy.

H.Testee can not use enamel or other makeup.

I. Please clean and disinfect the device after operating according to the User Manual (7.1).

6.3 Clinical restrictions

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this device may be inaccurate.

C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor resulted in serious error of SpO_2 measure.

D. The SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, for some patients with serious anemia may also report good SpO_2 measurement.

7 Maintain、transportation and storage

7.1 Cleaning and disinfecting

Using medical alcohol to wipe the device for disinfecting, nature dry or clean it with clean soft cloth.

7.2 Maintain

A Please clean and disinfect the device before using according to the User Manual (7.1).

B Please recharge the battery when the screen shows low-power (the battery power is) .

C Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is not regular used. It can extend the battery life following this guidance.

D The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3 Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not be transported mixed with toxic, harmful, corrosive materials.

B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~60°C; Relative Humidity: ≤95%.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally.	The finger is not properly positioned.	Place the finger properly and try again.
	The patient's SpO_2 is too low to be detected.	Try again,go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably.	The finger is not placed inside deep enough.	Place the finger properly and try again.
	The finger is shaking or the patient is moving.	Let the patient keep still.
The device can not be turned on.	The battery is drained away or almost drained away.	Please charge battery.
	The battery installation is incorrect.	Install the battery over again.
	The malfunction of the device.	Please contact the local service center.
The display is off suddenly	The battery is almost drained away.	Please charge battery.
	The device is set to shut down automatically in 5 seconds when there is no signal.	Normal.
The device can not be used for full time after charge	The battery is not full charged.	Please recharge the battery.
	The battery is damaged.	Please contact the local service center.
The battery can not be full charged even after 10 hours charging time.	The battery is damaged.	Please contact the local service center.

9 Key of symbols

Signal	Description
	Warning – See User Manual
$\%SpO_2$	The pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	Low-power indication
	The alarm sound indication

	The pulse sound indication
	Type BF
IPX1	Ingress of liquids rank
EC REP	EUROPEAN REPRESENTATIVE
	WEEE (2002/96/EC)
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
+	battery positive electrode
—	battery cathode electrode

10 Function specification

Information	Display Mode
The Pulse Oxygen Saturation（SpO_2）	2-digit digital OLED display
Pulse Rate（PR）	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
Waveform	Waveform OLED display
SpO_2 Parameter Specification	
Measuring range	0%～100%, (the resolution is 1%).
Accuracy	70%～100%：±2% ,Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	30bpm～250bpm, (the resolution is 1bpm)
Accuracy	±2 bpm or ±2% (select larger)
Safety Type	Interior Battery，BF Type
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.

Battery Requirement	
Voltage 3.6 rechargeable buttony battery × 1	
Battery working life	
Charge and discharge not less than 300 times.	
Dimensions and Weight	
Dimensions	46(L) × 40(W) × 29(H) mm
Weight	About 35g (with a rechargeable buttony battery)

Appendix A

Guidance and manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *CMS50QB* Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of *CMS50QB* Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The CMS50QB Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of CMS50QB Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the CMS50QB Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
 </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CMS50QB Pulse Oximeter is used exceeds the applicable RF compliance level above, the CMS50QB Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CMS50QB Pulse Oximeter.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *CMS50QB PULSE OXIMETER*

The *CMS50QB* Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *CMS50QB* Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *CMS50QB* Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.